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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,857	01/30/2004	David Lewis	248336US0DIV	3917
22850 7590 07/03/2007 OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER ALSTRUM ACEVEDO, JAMES HENRY	
			ART UNIT	PAPER NUMBER
			1616	
			NOTIFICATION DATE	DELIVERY MODE
			07/03/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/766,857	Applicant(s) LEWIS ET AL.	
	Examiner James H. Alstrum-Acevedo	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16,17 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16,17 and 28-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 16-17 and 28-33 are pending. Applicants previously cancelled claims 1-15 and 18-27. Applicants' have amended claim 16 to recite aerosol particles. This amendment does not materially change the claimed compositions, because all aerosols inherently comprise particles. Applicants have incorrectly described claim 17 as currently amended. No amendments have been made to claim 17. Receipt and consideration of Applicants' amended claim set and arguments/remarks submitted on January 12, 2007 are acknowledged.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 12, 2007 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1616

Claims 28-30 are indefinite because it is unclear what active compounds are being claimed. The use of comprising language to describe the active material suggests that Applicants are claiming unknown compounds wherein these unknown compounds comprise a moiety that is a beta-2 agonist, corticosteroid, or anti-cholinergic. The specification does not contain any disclosure of compounds that contain moieties identified as being a beta-2 agonist, corticosteroid, or anti-cholinergic. However, the specification does disclose active materials that are beta-2 agonists, corticosteroids, or anti-cholinergics in paragraph [0059].

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 16-17, 29, and 31-33 under 35 U.S.C. 102(b) as being anticipated by McNally et al. (U.S. Patent No. 5,653,961) **is maintained** for the reasons of record set forth on pages 3-4 of the previous office action mailed on January 18, 2006.

Response to Arguments

Applicant's arguments filed January 12, 2007 have been fully considered but they are not persuasive. Applicants' traversal of the rejections utilizing McNally (USPN 5,653,961) as the only or primary reference is based on the assertion that McNally fails to teach particles having an MMAD greater than 2 microns, wherein at least 40% of said particles have a diameter of less than 4.7 microns. The Examiner respectfully disagrees, because McNally discloses formulations in Examples 1-2 having a respirable fraction (i.e. the percent by weight of particles having an

aerodynamic particle size less than 4.7 microns)¹ ranging from 45% to 69%. A composition wherein 45% to 69% of the particles of said composition have an aerodynamic particle size less than 4.7 microns read on compositions having an MMAD greater than 2 microns, because 31-55% of the other particles in the composition would have an aerodynamic particle size greater than 4.7 microns. Thus, the median aerodynamic particle size would inherently be greater than 2 microns. This disclosure meets the limitations of claim 16 concerning the physical characteristics of the aerosol particles (see page 4 of the previous office action mailed on January 18, 2006). Regarding the different amounts of HFA 134a and HFA 227 (P134a and P227 in McNally), it is emphasized that in Table 4, McNally discloses various ratios of HFA 134a to HFA 227 ranging from 0:100 to 100:0, which encompasses Applicants' claimed range of HFA 134a to HFA227 ratios.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

¹ Respirable fraction is defined by McNally in column 4, lines 29-31. The cited definition has an obvious typographical error for the units of the particle size written as "mm" as opposed to μm , because it was well known at the time of McNally's publication date that particles with a size of greater than 10 microns are not respirable. See for example, (1) Abramson (U.S. Patent No. 3,095,355: e.g. col. 1, lines 34-38 in), (2) Hartley et al. (U.S. Patent No. 3,860,618: e.g. abstract or col. 1, lines 28-31 and 41-45), or (3) Radhakrishnan et al. (U.S. Patent No. 5,192,528: e.g. Fig. 1 and col. 6, lines 20-54).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 28 and 30 under 35 U.S.C. 103(a) as being unpatentable over McNally et al. (U.S. Patent No. 5,653,961) in view of Byron et al (U.S. Patent No. 5,190,029) is maintained for the reasons of record set forth on pages 3-4 and 6-7 of the previous office action mailed on January 18, 2006.

Response to Arguments

Applicant's arguments filed January 12, 2007 have been fully considered but they are not persuasive. Applicants' traversal of the rejections utilizing McNally (USPN 5,653,961) as the only or primary reference is based on the assertion that McNally fails to teach particles having an

Art Unit: 1616

MMAD greater than 2 microns, wherein at least 40% of said particles have a diameter of less than 4.7 microns. The Examiner respectfully disagrees, because McNally discloses formulations in Examples 1-2 having a respirable fraction (i.e. the percent by weight of particles having an *aerodynamic particle size less than 4.7 microns*)² ranging from 45% to 69%. A composition wherein 45% to 69% of the particles of said composition have an aerodynamic particle size less than 4.7 microns read on compositions having an MMAD greater than 2 microns, because 31-55% of the other particles in the composition would have an aerodynamic particle size greater than 4.7 microns. Thus, the median aerodynamic particle size would inherently be greater than 2 microns. This disclosure meets the limitations of claim 16 concerning the physical characteristics of the aerosol particles (see page 4 of the previous office action mailed on January 18, 2006). Regarding the different amounts of HFA 134a and HFA 227 (P134a and P227 in McNally), it is emphasized that in Table 4, McNally discloses various ratios of HFA 134a to HFA 227 ranging from 0:100 to 100:0, which encompasses Applicants' claimed range of HFA 134a to HFA227 ratios.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application

² Respirable fraction is defined by McNally in column 4, lines 29-31. The cited definition has an obvious typographical error for the units of the particle size written as "mm" as opposed to μm , because it was well known at the time of McNally's publication date that particles with a size of greater than 10 microns are not respirable. See for example, (1) Abramson (U.S. Patent No. 3,095,355: e.g. col. 1, lines 34-38 in), (2) Hartley et al. (U.S. Patent No. 3,860,618: e.g. abstract or col. 1, lines 28-31 and 41-45), or (3) Radhakrishnan et al. (U.S. Patent No. 5,192,528: e.g. Fig. 1 and col. 6, lines 20-54).

Art Unit: 1616

claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejections on the ground of nonstatutory obviousness-type double patenting of (1) claims 16-17 and 28-33 (all pending claims) as being unpatentable over claims 1-12, 14, and 16-29 of U.S. Patent No. 6,713,047; (2) claims 16-17 and 30-32 as being unpatentable over claims 1-14 and 22-24 of U.S. Patent No. 6,964,759; and (3) claims 16-17, and 28-32 as being unpatentable over claims 11-44 of U.S. Patent No. 6,713,047 (formerly copending application 09/831,888) **are maintained** because Applicants' have requested to hold these rejections in abeyance until it is clear what material the Examiner deems patentable. The specific rejected claims have been changed to reflect Applicants cancellation of claims 1-15 and 18-27.

Response to Arguments

Applicant's arguments filed January 12, 2007 have been fully considered but they are not persuasive. Applicants have traversed the above non-provisional obviousness-type double patenting rejections by asserting that there is allegedly nothing in the claims of the cited patents which would suggest Applicants' claimed aerosols. These are not substantive arguments, because these arguments fail to articulate the deficiencies allegedly present in the cited claims of

Art Unit: 1616

the cited U.S. patents that fail allegedly fail to render the rejected claims obvious. Mere argument in the absence of evidence is unpersuasive.

The provisional rejection on the ground of nonstatutory obviousness-type double patenting of claims 16-17 as being unpatentable over claims 1, 4-7, and 13 of copending Application No. 10/505,679 **is maintained** for the reasons of record set forth on pages 4-5 of the office action mailed on October 12, 2006.

Response to Arguments

Applicant's arguments filed January 12, 2007 have been fully considered but they are not persuasive. Applicants have not traversed the instant rejection and have requested that this rejection be held in abeyance. This rejection is maintained.

Other Matter

It is noted that Applicants' have amended claim 16 to recite "consisting of" language, however, the use of open transitional language in dependent claims 28-30 effectively reopens the claim language for the entire composition claimed. If Applicants' wish to utilize "consisting of" claim language it is respectfully suggested that this language is incorporated in the claims depending from claim 16 as well. It is also noted that claims 28-30 state that the active material comprises a beta-2 agonist (claim 28), a corticosteroid (claim 29), or an anti-cholinergic drug (claim 30). However, it seems Applicants intended to claim formulations wherein the active is a beta-2 agonist, corticosteroid, or an anti-cholinergic. The use of the word "comprises" suggests

Art Unit: 1616

Applicants are claiming formulations in which the active compound is some unidentified compound having a moiety that is a beta-2 agonist, corticosteroid, or an anti-cholinergic.

Conclusion

Claims 16-17 and 28-33 are rejected. No claims are allowed.

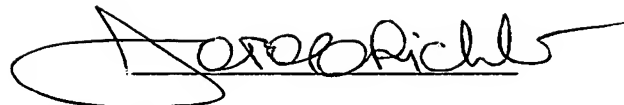
Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1616

James H. Alstrum-Acevedo
Patent Examiner
Technology Center 1600

A handwritten signature in black ink, appearing to read "Johann R. Richter", with a large, stylized loop at the beginning and a horizontal line underneath the signature.

Johann R. Richter
Supervisory Patent Examiner
Technology Center 1600